

REMARKS/ARGUMENTS

Applicant has amended the claims in order to re-organize and focus their subject matter, without prejudice to the prosecution of the canceled claims in a future application. Support for the claim amendments may be found throughout the specification; e.g., in paragraphs 52-54, 60-64 and in Example 10 on pages 29-32.

Hyperlink

The Examiner pointed out in the office action that paragraph 35 on page 7 improperly includes a hyperlink. Therefore, Applicants have deleted the reference to the website from paragraph 35 and added a statement that identifies the organization (namely, the National Center for Biotechnology) that operates the website and from which the software programs referred to in paragraph 35 may be obtained.

Rejections under 35 U.S.C. Section 112

The Examiner rejected Claims 60-61 and 64-71 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully traverses this rejection for the reasons set forth below.

"Muscodor-derived composition"

Specifically, the Examiner asserted that the term "Muscodor-derived composition" is vague and indefinite. The claims, as amended, do not include the above term, rendering this rejection moot. Therefore, Applicant respectfully requests its reconsideration and withdrawal.

"exposing the organism or the habitat of the organism to a pesticidally effective amount"

The Examiner also asserts that the phrase "exposing the organism or a habitat of the organism to a pesticidally effective amount" is indefinite. In particular, the Examiner notes that "exposing" does not set forth whether contact with the target is or is not achieved." Applicant notes that the term "exposing" is used throughout the specification, instead of the term "contacting," to emphasize that the effective amount of the claimed composition does not have to be in contact initially with the target organism. Instead, contact may be eventual. In particular, in Example 10, the plug of target organism and the filter paper loaded with the claimed composition are not placed in direct contact. Instead, the target organism is exposed to the claimed composition, which, as a volatile in a sealed environment, eventually makes contact with the target organism. Similarly, in paragraphs 97-98, Applicant describes *exposure* of target organisms to a synthetic mixture of volatile organic compound, in which a microcup of volatile organic compounds is placed in a Petri plate 2-3 cm from the test organism. Tests on the head space above the nutrient medium in the plate indicated the IC₅₀ for each target organism. Because the meaning of the term "exposing" is not vague or indefinite in light of its use in the specification, Applicant respectfully requests reconsideration and withdrawal of this rejection.

In addition, the Examiner notes that the term "pesticidally effective amount" is not delineated with particularity, especially since a maximum but not a minimum is defined for some of the volatile compounds and the pest is not identified with any particularity."

The current claims cover microbes only and use the term "effective amount." The term "effective amount" is defined on page 5, paragraph 27 of the specification. As described in more detail below in the section regarding the enablement rejection, it is a matter of routine experimentation to determine the amount of the claimed composition needed to inhibit the growth of a microbe in a particular environment. The specification also provides sufficient guidance as to how to test efficacy of volatile organic compounds against other organisms; e.g., in Example 10. In addition, even without this guidance, it is within the skill of those of ordinary skill in the art to conduct straightforward experiments in which concentrations of the claimed volatile organic compound(s) are varied to determine effective amounts. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw this rejection.

"toxic mold," "building materials," and "spaces between building materials"

Finally, the Examiner asserts that the term "toxic mold" is vague and indefinite since "there is no indication as to the target of the toxicity." The claims, as amended, do not include the term "toxic mold," rendering this part of the rejection moot.

In addition, the Examiner asserts that the terms "building materials" and "spaces between building materials" cannot be readily assessed and include "paper, cardboard, metal, molding clay, wood, plastic, bricks and concrete, etc." Applicant has amended the claims to refer solely to buildings. This amendment also renders this part of the rejection moot. Therefore, Applicant respectfully requests its reconsideration and withdrawal.

Rejections under 35 U.S.C. Section 112, first paragraph – Written Description

The Examiner rejected Claims 60-61 and 64-71 under 35 U.S.C. Section 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner notes:

The claims are broadly drawn to the use of certain organic volatile compounds to inhibit the growth of *any* microbe, *any* insect and *any* nematode.... In contrast, the specification only provides guidance for the treatment of certain fungi, a few specific insects, a few specific bacteria and one nematode *in vitro*, using specific mixtures of volatile compounds. No guidance is presented regarding the structure/function relationship between the use of one or a few volatile compounds in combination in undisclosed amounts and their application *in vivo*, for the inhibition of growth of microbes having as their habitat an animal and/or human and cause diseases." (Emphasis added.)

Applicant notes that the claims, as amended, do not recite any and every microbe but simply a microbe, which may be interpreted as one or more microbes. In addition, the amended claims are limited to a method for inhibiting the growth of a microbe in certain habitats (on plants, in fruit, etc.), as described in paragraphs 60-64 of the specification, and do not include an animal as one of these habitats.

As to the Examiner's assertion that the specification does not provide sufficient guidance as to the relationship between one or a few volatile organic compounds and their application *in vivo*, Tables 7 and 8 show that the claimed volatile organic compounds; namely, isobutyric acid, 2-methyl-1-butanol and 3-methyl-1-butanol, either alone or in combination with other volatile organic compounds, such as isobutyl alcohol, ethyl propionate and ethyl butyrate, inhibit the growth of a microbe. Further, the present application claims priority to an application, now granted as U.S. Patent No. 6,911,338, that discloses testing of the *Muscodor* organism and its volatiles against various microbes in the Petri plate system used in Example 10. Further examples in the '338 patent show that the *Muscodor* organism is also effective against these organisms in soil and in sealed boxes containing apples infected with a common post harvest pathogen. Thus, the Petri plate method is a good predictor of how the volatile organic compound(s) described in the present application would perform in other circumstances.

Finally, the Examiner states, "There is no clear indication that one or more of the recited compounds regardless of their source and in trace amounts would have the required inhibitory effects." The written description does not limit the volatile organic compounds or mixtures thereof to a particular source. Instead, it describes using synthetic mixtures to mimic the pesticidal properties of *M. albus*. See; e.g., paragraph 50. The experiments in Example 10 were conducted using synthetic sources of the tested volatile organic compounds, such that source is not relevant to the claimed composition. In addition, Applicant has removed the phrase "Muscodor-derived" from the amended claims to avoid any implication that the claimed volatile organic compounds must be obtained from *Muscodor*. For all of the reasons discussed above, Applicant respectfully

requests reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. Section 112, first paragraph .

Rejections under 35 U.S.C. Section 112, second paragraph – Enablement

The Examiner also rejected Claims 60-61 and 64-71 under 35 U.S.C. Section 112, first paragraph, asserting that the specification "does not reasonably provide enablement for the inhibition of any microbe, insect, or nematode using certain volatiles singly or in combination in any amount." Applicants respectfully traverse this rejection, addressing it insofar as it applies to the subject matter of the amended claims.

Specifically, the Examiner notes that the application "does not provide sufficient guidelines or teachings for the inhibition of any and all microbes, including intracellular bacteria such as Mycobacterium or Chlamydia or pathogenic bacteria, such as Listeria, Legionella Borrelia burgorferi or any and all viruses..." However, case law holds that the enablement requirement is met "if the description enables any mode of making and using the invention." *See Johns Hopkins University v. Cellpro*, 152 F.3d 1342, 1361, 47 U.S.P.Q. 2d 1705 (Fed. Cir. 1998)(quoting *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q. 2d 1300, 1304 (Fed. Cir. 1991). (A copy of the case is enclosed for the Examiner's convenience.) In other words, the specification does not need to include examples of the inhibition of all microbes in order to properly enable the claims. Instead, according to case law, the specification simply needs to provide a reasonable amount of guidance, in light of the prior art and knowledge of one of ordinary skill in the art at the time of filing the application, to practice the invention. The specification enables a mode for using the invention in Example 10 and provides

sufficient guidance so that one of ordinary skill in the art could practice the claimed invention by following the guidelines set forth in the specification. As noted above, the Petri plate system in Example 10 is predictive of how the volatile organic compound(s) will act in various other circumstances.

The Examiner also asserts that the amount of experimentation required to practice the invention is undue. Applicant respectfully points out that even if one of skill in the art would have to perform experiments to practice the invention, according to the Federal Circuit, "The test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention." *See Johns Hopkins University v. Cellpro*, 152 F.3d 1342, 1360, 47 U.S.P.Q. 2d 1705 (quoting *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75. F.3d 1558 , 1564, 37 U.S.P.Q. 2d 1618, 1623 (Fed. Cir. 1996)).

In the present case, one of ordinary skill in the art, using the protocol described in Example 10 and publicly available knowledge as to growing pathogens, could determine effective amounts of the claimed volatile organic compounds against various microbes. To support this argument, attached is a Declaration under 37 C.F.R. Section 1.132, including Exhibits A-C, describing straightforward experiments that show efficacy of the claimed volatile organic compounds; namely, isobutyric acid and 2-methyl-1-butanol, both singly and in various combinations, such as with each other and with isobutyl

alcohol, and against various organisms, using protocols that are identical or very similar to those described in Example 10.

The experimental results in the exhibits attached to the declaration show that determining an effective amount of the claimed compositions in different circumstances and against different microbes is a matter of routine screening that involves varying the amount of the volatile organic compound(s) to determine an effective amount for inhibiting the target microbe. Although this might be considered "considerable experimentation," it is not undue, as one of ordinary skill, based on both the specification and publicly available methodologies available at the time of filing the patent application, would know how to vary dosages to determine at which concentration the composition at hand is effective and how to propagate various microbes for use as test organisms. For all of the reasons set forth above, Applicant respectfully requests reconsideration and withdrawal of the rejection of Claims 60-61 and 64-71 under 35 U.S.C. Section 112, second paragraph.

Rejections under 35 U.S.C. Section 102(b)

Nandi Reference

The Examiner rejected Claims 60, 64 and 70 as anticipated by Nandi, et al. The claims, as amended, do not disclose use of ethyl butyrate, alone, to inhibit fungi. Because the amendments render the rejection moot, Applicant respectfully requests its reconsideration and withdrawal.

Rathore Reference

The Examiner rejected Claims 64 and 70 as anticipated in light of Rathore. The claims, as amended, do not disclose use of ethyl butyrate and/or ethyl propionate, alone, to inhibit fungi. Because the amendments render the rejection moot, Applicant respectfully requests its reconsideration and withdrawal.

Robinson Reference

The Examiner rejected Claims 64 and 70 in light of Bartelt. The claims, as amended, do not disclose use of isobutyl alcohol, alone, to inhibit fungi. Because the amendments render the rejection moot, Applicant respectfully requests its reconsideration and withdrawal.

Bartelt, Landolt and Nout References

The Examiner rejected Claims 60, 64 and 65 as anticipated in light of Bartelt, Claims 64 and 65 as anticipated in light of Landolt, and Claims 64-67 as anticipated in light of Nout. The claims, as amended, do not recite inhibition of insects using volatile organic compounds. Because the amendments render these rejections moot, Applicant respectfully requests their reconsideration and withdrawal.

In light of the above-amendments and remarks, Applicant believes that each of the presently pending claims in this application is in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

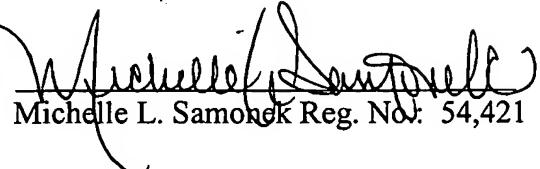
Applicant does not believe any fees are required by this submission, but if Applicant is mistaken, any required fees may be charged to deposit account 50-2767. If

the Examiner has any questions regarding this communication, she is invited to contact the undersigned at (916) 325-4553.

Respectfully submitted,

Dated: 7/5/01

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